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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,059	03/02/2004	Sang Yup Lee	4240-103	3338

23448 7590 04/19/2006

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/791,059

Applicant(s)

LEE ET AL.

Examiner

Agnes B. Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 2/2/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 6, 7, 9-11, 13-15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6, 7, 9, 10, 11, 13-15, 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This final office action is in response to the paper filed on 02/02/2006.

Claim 1, 3, 4, 6, 7, 9, 10, 11, 13-15, and 18 are pending.

Claims 2, 5, 8, 12, 16, and 17 are canceled.

All Rejections and Objections not mentioned in this office action has been
withdrawn.

All new Rejections and Objections are necessitated by the Applicants'
amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 3, 4, 6-11, and 18 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 3, 4, 6, 7, 9, 10, 11, and 18, Applicants amended the claims to state "at least one of the forty-one sHSPs" and still, the possible maximum amount of proteins that could be used at the same time in the method is not provided or particularly pointed out (whether forty one or only one protein is used at the same time in the method claimed). Therefore, the clarification as to the number of proteins should be provided.

New Matter

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7 and 18 introduce a new matter because nowhere in the specification there is a mention that a gel with at least **50% increased number** of spots as compared to a gel obtained for a corresponding sample composition is presented.

In case of the evidence to the contrary, examiner asks the Applicants to specifically point out the 50% value in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lubman et al. (U.S. 2002/0098595 A1).

Lubman et al. teach that heat shock proteins have been identified from the 2-D gel, See [0137] page 15; and provide a method analogous to the 2-D gel, where the method can be used for proteome analysis. See [0151] page 17.

Therefore, it would have been obvious to a person skilled in the art to design a method for the analysis of proteomes using 2-D gel electrophoresis where the method is analogous to the 2-D gel and uses heat shock proteins as disclosed by Lubman et al.

Applicants argue that the mere fact that heat shock proteins can be identified by 2-D gel as the target protein does not in any way teach or suggest that heat shock proteins can be added for the analysis of proteomes by 2D gel electrophoresis, and there is no evidence that one skilled in the art would have been motivated to use it for the analysis of proteomes by 2D gel electrophoresis.

Examiner respectfully disagrees, because even though the exact heat shock proteins claimed in the instant invention are not pointed out in Lubman, there is a heat shock protein HS27 that is used in Lubman's analysis of proteomes using 2-D gel electrophoresis. Therefore, the rejection stands.

Claims 1, 3, 4, 6, 7, 10, 11, and 13-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Willsie et al., Small Heat Shock Protein p26 Associates with Nuclear Lamins and HSP70 in Nuclei and Nuclear Matrix Fractions from Stressed Cells, J. Cellular Biochem. (2002), 84, p. 601-614, in view of Kitagawa et al., Escherichia coli

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Small Heat Shock Proteins, IbpA and IbpB, Protect Enzymes From Inactivation by Heat and Oxidants, Eur. J. Biochem. (2002), 269, p. 2907-2917.

Willsie et al. teach α -crystallin protein p26 HSP bound to nuclear matrix proteins derived from embryos that were subject to 2-D gel electrophoresis, see page 606, right column and page 607, right column. Therefore, Willsie et al. teach compositions of small heat shock proteins including α -crystallin protein p26 from Table 1. Willsie et al. teach a method of 2-D gel electrophoresis comprising adding small HSPs to a nuclear matrix protein mixture and subjecting the mixture to 2-D gel electrophoresis, wherein the sHSP is α -crystallin p26 from Table 1.

Claims 10 and 11 are included in this rejection because sHSPs were effective.

Willsie et al. teach method of using sHSPs as inhibitors of protein degradation because in control blots the proteins were degraded. See Figure 2, page 606, and Figure 3, page 607. Willsie et al. does not teach the method for the gel electrophoresis wherein the protein mixture is total protein of specific cells of prokaryotes and eukaryotes, such as E.coli and Pseudomonas.

Kitagawa et al. teach two small heat shock proteins of E. coli, IbpA and IbpB. See page 2909, right paragraph (*Expression and purification of His-IbpA and His-IbpB* section). Kitagawa et al. teach two small heat shock proteins of E. coli, IbpA and IbpB, but do not teach 2-D gel electrophoresis.

It would have been obvious to a person skilled in the art to design a method for the 2-D gel electrophoresis as disclosed by Willsie et al. and use a protein mixture of

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lbpA or lbpB (sHSPs) from E.coli as disclosed by Kitagawa et. el. because small heat shock proteins help to stabilize other proteins and remain associated with unfolded proteins in 2-D gel electrophoresis.

Applicants argue that Willsie does not in any way disclose, teach or suggest that p26 can be used to prevent protein degradation; and that there is no teaching that p26 can be added to the protein mixture, so as to prevent protein degradation in the 2D gel electrophoresis; and that there is no teaching that p26 can be added to the protein mixture to inhibit or target protein degradation.

Also, Applicants argue that Kitagawa does not suggest gel electrophoresis sample composition that is resistant to protein degradation, comprising protein that is susceptible to degradation by protease, with protease being present in the sample composition containing small heat shock protein as recited in claim1, or as required in claims 3, 4, and 6.

Examiner respectfully disagrees because there is a strong motivation to design a method for the 2D gel electrophoresis by using sHSP, so as to prevent protein degradation as presented in the arguments above based on the references of Willsie et al. in view of Kitagawa et al. (as above)

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have

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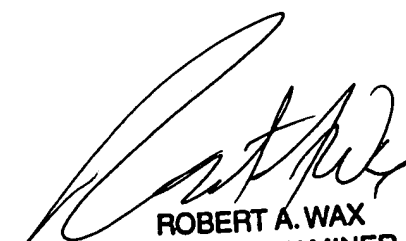
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any questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-217-9197.

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ROBERT A. WAX
PRIMARY EXAMINER